



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

D1409 B

April 9, 1997

WARNING LETTER
CHI-25-97

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jacob Iftner
Route 2, Box 71
Barry, Illinois 62312

Dear Mr. Iftner:

An inspection of your swine producing operation, conducted by Investigator Mark G. Peterson on March 31, 1997, found that you offered hogs for sale for slaughter as human food in violation of Section 402(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (Act).

On or about December 10, 1997, you sold a hog for slaughter through[]. This animal was subsequently transported from [IL, to [], where it was slaughtered for human food. USDA analysis of tissue samples collected from that animal identified the presence of 0.43 parts per million (ppm) sulfamethazine in the muscle tissue. The established tolerance for sulfamethazine in swine is 0.10 ppm. The presence of this drug in the edible tissue from this animal causes the food to be adulterated under section 402(a)(2)(D) of the Act.

The above is not intended as an all-inclusive list of violations. As a producer of animals for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations, may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes official notification under the law.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold, and subsequently offered for sale in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard Harrison, Acting Director, Compliance Branch.

Sincerely,

Raymond V. Mlecko
District Director

- cc: Dr. Judd Giezentanner
North Central Region
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- cc: Richard Hull, DVM
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